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April 15, 2004

Michael O. Leavitt, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building, 1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on the HPV Test Plan for the category Alkyl Nitriles

Dear Administrator Leavitt:

The following comments on the joint test plan by Eastman and Solutia for the Alkyl nitriles category are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

Eastman Chemical Company and Solutia Inc. submitted their test plan on December 19, 2003, for the category Alkyl nitriles consisting of Propionitrile (CAS No. 107-12-0), Butyronitrile (CAS No. 109-74-0) and Isobutyronitrile (CAS No. 78-82-0). Propionitrile is manufactured by Solutia at a single site and butyronitrile and isobutyronitrile are manufactured by Eastman at a single site. Alkyl nitriles are then sold to other manufacturers for chemical conversion to products such as pharmaceuticals, industrial solvents, and dielectric fluid, and conversion to industrial chemicals (butyric acid, pharmaceuticals, organics). We are encouraged and delighted by the collaboration between Eastman and Solutia. This approach to hazard assessment avoids separate and/or duplicative testing which would violate the basic tenets of animal welfare and the HPV program. For this test plan, both companies have done an exemplary job in adhering to animal welfare principles set forth by the EPA, including EPA's stated goal that HPV participants "maximize the use of existing and scientifically adequate data to minimize further testing" (Wayland 1999).

Eastman and Solutia have submitted a comprehensive analysis of Alkyl nitriles by compiling substantial amounts of existing data from a variety of sources and combining three chemicals with similar chemical, pharmacological, and toxicological properties into a single category for purposes of the HPV program. This approach demonstrates a thoughtful analysis by both companies, in addition to being a scientifically valid analysis of a chemical's toxicity and adequate for a screening level program. Information from

existing data or data derived from estimation models for all SIDS endpoints have led to the conclusion that no additional testing is required under the HPV Challenge program.

We applaud Eastman and Solutia for using repeated dose and reproduction toxicity data for propionitrile to bridge data gaps for butyronitrile and isobutyronitile. Given the close relationship, i.e. physicochemical properties and toxicity, between these three alkyl nitirles, this approach is justified and commended. We concur that no additional testing is needed for the purposes of the HPV program. Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 327, or via e-mail at meven@pcrm.org.

Sincerely,

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Research Analyst

Chad B. Sandusky, Ph.D.
Director of Toxicology and Research

References

Wayland, S.H., Letter to manufacturers/importers, October 14, 1999, http://www.epa.gov/chemrtk/ceoltr2.htm.